IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION, NOVARTIS AG, and NOVARTIS PHARMA AG, Plaintiffs, v. ACTAVIS, INC. and ACTAVIS ELIZABETH LLC, Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis AG, and Novartis Pharma AG (collectively, "Novartis"), for its Complaint against Defendants Actavis, Inc. ("Actavis U.S.") and Actavis Elizabeth LLC ("Actavis Elizabeth") (collectively, "Actavis") hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent No. 6,465,504 ("the '504 Patent"), arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281.

2. This action relates to Abbreviated New Drug Application ("ANDA") No. 208697 filed by Actavis Elizabeth LLC with the U.S. Food and Drug Administration ("FDA") for approval to market 90 mg, 180 mg, and 360 mg deferasirox tablets ("Actavis Generic

Deferasirox Tablets"), generic versions of the 90 mg, 180 mg, and 360 mg Novartis JADENU® drug product, prior to expiration the '504 patent.

PARTIES

3. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Health Plaza, East Hanover, New Jersey.

4. Novartis Corporation is a corporation existing under the laws of the State of New York, with its principal place of business at 608 5th Avenue, New York, New York.

5. Novartis AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

6. Novartis Pharma AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

7. Upon information and belief, Actavis U.S. is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Actavis U.S. was formerly known as Watson Pharmaceuticals, Inc., which changed its corporate name to Actavis, Inc. in 2013.

8. Upon information and belief, Actavis U.S. itself, and through its wholly-owned subsidiary and agent, Actavis Elizabeth, develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

9. On information and belief, Actavis U.S. and Actavis Elizabeth have at least one officer and/or director in common.

10. Upon information and belief, Actavis Elizabeth is a company organized and existing under the laws of Delaware, having its principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202.

11. Upon information and belief, Actavis Elizabeth is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Actavis Elizabeth is a wholly-owned subsidiary of Actavis U.S. and is controlled and/or dominated by Actavis U.S. Upon information and belief, Actavis Elizabeth develops, manufactures, distributes and/or sells generic versions of branded pharmaceutical products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Actavis U.S. Upon information and belief, Actavis U.S. established Actavis Elizabeth for the purposes of developing, manufacturing, and distributing its generic drug products throughout the United States, including in this judicial district.

12. Actavis U.S. and Actavis Elizabeth are collectively referred to hereafter as "Actavis."

JURISDICTION AND VENUE

13. This action arises under the patent laws of the United States of America, 35 U.S.C. §§ 100, *et seq.* This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

14. This Court has personal jurisdiction over Actavis U.S. because, upon information and belief, Actavis U.S. has its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. Actavis U.S. is registered to do business in the State of New Jersey, Department of Treasury: Division of Revenue and Enterprise Services, under entity number 0101005391. Upon information and belief, R&D activities of Actavis U.S. occur in, *inter alia*, Elizabeth, New Jersey. Upon information and belief, Actavis U.S. manufactures finished products in Elizabeth, New Jersey. Upon information and belief, Actavis Elizabeth purposefully has conducted and continues to conduct business in this judicial district.

15. On information and belief, Actavis, Inc. is registered as a manufacturer and wholesale drug distributor in the State of New Jersey under Registration Number 5003854.

16. This Court has personal jurisdiction over Actavis Elizabeth because, upon information and belief, Actavis Elizabeth has its principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202. Actavis Elizabeth is registered to do business in the State of New Jersey, Department of Treasury: Division of Revenue and Enterprise Services, under entity number 0600272818. Upon information and belief, Actavis Elizabeth purposefully has conducted and continues to conduct business in this judicial district.

17. Upon information and belief, Actavis U.S. and Actavis Elizabeth operate as an integrated, unitary generic pharmaceutical business.

18. Upon information and belief, Actavis distributes for sale hundreds of drug products through the United States, including in this judicial district.

19. Upon information and belief, Actavis U.S. and Actavis Elizabeth derive substantial revenue from generic pharmaceutical products that are sold, used, and/or consumed within New Jersey.

20. This Court also has personal jurisdiction over Actavis U.S. because, among other things, it has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of a tortious act of patent infringement in filing ANDA No. 208697 that has led to foreseeable harm and injury to Novartis Pharmaceuticals Corporation, a corporation with its principal place of business in New Jersey.

21. Upon information and belief, Actavis U.S. and Actavis Elizabeth operate as an integrated, unitary generic pharmaceutical business.

22. Upon information and belief, Actavis U.S. and Actavis Elizabeth derive substantial revenue from generic pharmaceutical products that are sold, used, and/or consumed within New Jersey.

23. Upon information and belief, Actavis U.S. and Actavis Elizabeth will manufacture, market, and/or sell within the United States the Actavis Generic Deferasirox Tablets described in ANDA No. 208697 if FDA approval is granted. If ANDA No. 208697 is approved, the Actavis Generic Deferasirox Tablets charged with infringing the Patents-in-Suit, would, among other things, be marketed and distributed in New Jersey, prescribed by physicians practicing in New Jersey, and dispensed by pharmacies located within New Jersey, and/or used by persons in New Jersey, all of which would have a substantial effect on New Jersey. For example, upon information and belief, Actavis knows that the Novartis JADENU® product has been and will be distributed and used in New Jersey. Because of, among other things, New Jersey's generic substitution laws, upon approval, Actavis intends to replace those sales of JADENU® with its Actavis Generic Deferasirox Tablets.

24. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Actavis U.S. and Actavis Elizabeth.

THE '504 PATENT

25. On October 15, 2002, the U.S. Patent and Trademark Office duly and legally issued the '504 Patent, entitled "Substituted 3,5-Diphenyl-1,2,4-Triazoles and Their Use as Pharmaceutical Metal Chelators." A true and correct copy of the '504 Patent is attached hereto as **Exhibit A**. The claims of the '504 Patent cover the compound deferasirox. The claims of the '504 Patent are valid and enforceable.

26. Novartis is the owner of the entire right, title and interest in the '504 Patent by assignment, and possesses the right to sue for and obtain equitable relief and damages for infringement of the '504 Patent.

JADENU®

27. Novartis is the holder of approved New Drug Application ("NDA") No. 206910 ("JADENU® NDA") by which the FDA granted approval for the marketing and sale of 90 mg, 180 mg, and 360 mg strength deferasirox tablets, which Novartis markets in the United States under the trade name "JADENU®". JADENU® was approved by the FDA on March 30, 2015.

28. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '504 Patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to JADENU®.

29. The composition and formulation for JADENU® is covered by certain claims of the '504 Patent. By way of example, the active ingredient in JADENU®, deferasirox,

has the chemical name of 4-[3,5-bis(2-hydroxyphenyl)-[1,2,4]triazol-1-yl]benzoic acid, which is covered by at least claim 5 of the '504 patent. *See e.g.*, '504 patent, claim 5 ("A compound according to claim 4 which is 4-[3,5-bis(2-hydroxyphenyl)-[1,2,4]triazol-1-y]benzoic acid, or a pharmaceutically acceptable salt thereof."); *see also* claims 1-6, 8, and 9.

ACTAVIS'S GENERIC DEFERASIROX TABLETS

30. By letter dated November 20, 2015 ("the Notice Letter"), Actavis notified Novartis that it had submitted ANDA No. 208697 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, and sale of 90 mg, 180 mg, and 360 mg generic deferasirox tablets before the expiration of the '504 Patent. Upon information and belief, Actavis intends to engage in the commercial manufacture, use, and sale of its 90 mg, 180 mg, and 360 mg generic deferasirox tablets for oral suspension promptly upon receiving FDA approval to do so.

31. The active ingredient in the Actavis Generic Deferasirox Tablets is deferasirox.

32. By filing ANDA No. 208697, Actavis has necessarily represented to the FDA that the Actavis Generic Deferasirox Tablets have the same active ingredient as JADENU®, dosage form, and strengths as JADENU®, and are bioequivalent to JADENU®.

33. In the Notice Letter, Actavis notified Novartis that its ANDA contained a "Paragraph IV certification" asserting that, in Actavis's opinion, certain claims of the Patents-in-Suit are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of the Actavis Generic Deferasirox Tablets.

34. In the Notice Letter, however, Actavis does not contest infringement of claims 1-6, 8 and 9 of the '504 Patent. These claims are directed to deferasirox, including the compound of deferasirox and pharmaceutical compositions of deferasirox.

35. Actavis has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2) by filing ANDA No. 208697 under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and/or sale of the Actavis Generic Deferasirox Tablets before the expiration of the term of the '504 Patent.

36. The sale or offer for sale of the proposed Actavis Generic Deferasirox Tablets for which Actavis seeks approval in its ANDA will infringe one or more claims of the '504 Patent.

37. Novartis is entitled under 35 U.S.C. § 271(e)(4) to full relief from Actavis's acts of infringement, including an Order by this Court ensuring that the effective date of any approval of ANDA No. 208697 relating to the proposed Actavis Generic Deferasirox Tablets shall not be earlier than the expiration of the '504 Patent.

38. This Complaint is being filed before the expiration of the forty-five days from the date Novartis received the Notice Letter.

COUNT ONE: INFRINGEMENT OF THE '504 PATENT

39. Novartis hereby realleges and incorporates by reference the allegations of paragraphs 1-38 of this Complaint.

40. Actavis's submission of ANDA No. 208697 to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Generic Deferasirox Tablets, which is a drug claimed in the '504 Patent, prior to the expiration of the

'504 Patent, constitutes infringement of at least claims 1-6, 8 and 9 of the '504 Patent under 35 U.S.C. § 271(e)(2)(A).

41. Upon FDA approval of Actavis's ANDA No. 208697, Actavis will further infringe the '504 Patent under 35 U.S.C. § 271(a), (b) and/or (c), by making, using, offering to sell, and selling its 90 mg, 180 mg, and 360 mg generic deferasirox tablets in the United States and/or importing such tablets into the United States.

42. By way of example, the active ingredient in Actavis Generic Deferasirox Tablets is deferasirox. Deferasirox has the chemical name of 4-[3,5-bis(2-hydroxyphenyl)-[1,2,4]triazol-1-yl]benzoic acid and is covered by at least claim 5 of the '504 patent. *See e.g.*, '504 patent, claim 5 ("A compound according to claim 4 which is 4-[3,5-bis(2-hydroxyphenyl)-[1,2,4]triazol-1-yl]benzoic acid, or a pharmaceutically acceptable salt thereof."); *see also* claims 1-4, 6, 8, and 9 (collectively, with claim 5, "the Asserted Claims"). Accordingly, the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Generic Deferasirox Tablets will directly infringe at least the Asserted Claims of the '504 patent.

43. Upon FDA approval of Actavis's ANDA No. 208697, Actavis will indirectly infringe the Asserted Claims of the '504 Patent by inducing infringement and/or contributing to infringement of the '504 Patent by others, including manufacturers, distributors, healthcare professionals, and/or patients. By way of example, upon information and belief, the Actavis Generic Deferasirox Tablets includes a product label that will instruct how to use the Actavis Generic Deferasirox Tablets. For example, upon information and belief, the product label instructs that the product to be used—the Actavis Generic Deferasirox Tablets—has the active ingredient of deferasirox and has the chemical name of 4-[3,5-bis(2-hydroxyphenyl)-[1,2,4]triazol-1-yl]benzoic acid, which is the same compound covered by at least the Asserted

Claims of the ’504 patent. *See e.g.*, ’504 patent, claim 5 (“A compound according to claim 4 which is 4-[3,5-bis(2-hydroxyphenyl)-[1,2,4]triazol-1-yl]benzoic acid, or a pharmaceutically acceptable salt thereof.”); *see also* claims 1-4, 6, 8, and 9. The Actavis Generic Deferasirox Tablets containing deferasirox are specially made to infringe at least the Asserted Claims of the ’504 patent, and have no substantial non-infringing use. Further, on information and belief, Actavis is and has been aware of the ’504 Patent prior to the date of this complaint, and knows (or is willfully blind to the fact) that the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Generic Deferasirox Tablets will constitute infringement of at least the Asserted Claims of the ’504 Patent. Upon information and belief, this specific intent is reflected through, among other things, the ’504 Patent’s listing in the Orange Book, prior litigation with Novartis related to the ’504 Patent, and Actavis’s Notice Letter, which does not contest infringement of the Asserted Claims.

44. If Actavis’s infringement of the ’504 Patent is not enjoined, Novartis will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Novartis prays that this Court grant the following relief:

1. A judgment that Actavis has infringed one or more claims of the ’504 Patent, and Actavis’s submission of ANDA No. 208697, and Actavis’s making, using, offering to sell, or selling in the United States, or importing into the United States the Actavis Generic Deferasirox Tablets, will infringe one or more claims of the ’504 Patent;

2. A judgment that the ’504 Patent is valid and enforceable;

3. An order pursuant to 35 U.S.C. §271(e)(4)(A) providing that the effective date of any approval of ANDA No. 208697 shall be a date which is not earlier than the latest

expiration date of the '504 Patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled;

4. An order restraining and enjoining Actavis, its officers, agents, attorneys and employees, and those acting in privity or concert with Actavis, from engaging in the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of the Actavis Generic Deferasirox Tablets, until after the latest expiration date of the '504 Patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled;

5. Damages or other monetary relief to Novartis if Actavis engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Actavis Generic Deferasirox Tablets before the latest expiration date of the '504 Patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled;

6. Costs and reasonable attorneys' fees relating to this action pursuant to 35 U.S.C. §§ 271(e)(4) and 285; and

7. Such other and further relief as the Court may deem just and proper.

DATED: DECEMBER 31, 2015

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is the subject of the following actions:

- *Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis AG, Novartis Pharma AG v. Actavis, Inc. and Actavis Elizabeth LLC*, C.A. No. 1:12-cv-00366-RGA-CJB, (D. Del.).
- *Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis AG, Novartis Pharma AG v. Actavis, Inc. and Actavis Elizabeth LLC*, C.A. No. 1:15-cv-01219-UNA, (D. Del.).

DATED: DECEMBER 31, 2015

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